ETEX Corporation Medical Device Special 510(k) Submission
α-BSM Bone Substitute Material
K072636

510(k) SUMMARY AS REQUIRED UNDER 21 CFR 807.87(h)

OCT 23 2007

1. **Submitted By:** ETEX Corporation
38 Sidney Street, 3rd Floor
Cambridge, MA 02139

Contact Person: Pamela W. Adams, R.A.C.
Senior Vice President and Chief Operating Officer

Date Prepared: September 12, 2007

FDA Establishment Number: 1225112

2. **Proprietary Name:** α-BSM Bone Substitute Material
Common Name: Bone Void Filler
Device Class: Class II
Product Code: MQV

3. **Legally Marketed Device for Substantial Equivalence Comparison:**
Product: α-BSM Bone Substitute Material
Product Code: MQV
Device Class: Class II
Manufacturer: ETEX Corporation
510(k) #: K011048

4. **Comparison to the Predicate Device:**
The subject α-BSM Bone Substitute Material is a synthetic bone substitute material that is substantially equivalent to α-BSM Bone Substitute Material cleared in K011048. Both α-BSM have the same indicated use; use the same operating principle; incorporate the same materials; have the same shelf life; are sterilized using the same processes; and have the same manufacturer.

Modifications in the subject α-BSM from the predicate device are minor modifications in labeling, IFU, and change in part numbers.

5. **Device Description:**
α-BSM Bone Substitute Material is a synthetic, biocompatible calcium phosphate implantable paste that hardens at body temperature and converts to an apatitic calcium phosphate. It is provided in single use packages containing either 2.5, 5.0 or 10 grams (nominal) of α-BSM

powder in a mixing bulb, sterile mixing solution, an appropriately sized syringe, and a 16 gauge needle.

α-BSM Bone Substitute Material is supplied sterile for single patient use. The product is packaged in a clear plastic sterilization pouch (with a second outer sterility barrier) containing: a unit does of sterile α-BSM Bone Substitute Material (dry, white powder) contained with an elastomeric (silicone) mixing bulb (available in 2.5, 5.0 or 10cc dose sizes) with a septum closure, a sterile syringe, a 16 gauge needle, and a vial of sterile saline. The saline is injected aseptically into the mixing bulb and the material is mixed by kneading the bulb with the fingers. Once the liquid and powder are well mixed, the bulb is opened and the material, now in paste form, can be administered to the site via a syringe or by manual application. The material can be shaped into the desired form prior to application or shaped *in situ* in the defect. The setting process occurs *in vivo* at neutral pH and is non-exothermic and non-caustic.

α-BSM Bone Substitute Material is synthesized from reagent grade inorganic raw materials composed of salts of calcium and phosphates. There are no substances of biological origin used in the synthesis or processing of the product. No additional preservatives or medicinal substances are present.

6. Indications for Use

α-BSM Bone Substitute Material is indicated for filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. α-BSM Bone Substitute Material is a bone graft substitute that resorbs and is replaced with bone during the healing process.

7. Substantial Equivalence

In summary, the α-BSM Bone Substitute Material described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2007

ETEX Corporation
% Ms. Pamela W. Adams, R.A.C.
Senior Vice President & Chief Operating Officer
38 Sidney Street
Cambridge, MA 02139

Re: K072636
Trade/Device Name: α-BSM® Bone Substitute Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: September 17, 2007
Received: September 24, 2007

Dear Ms. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known) **K072636**

Device Name α-BSM® Bone Substitute Material

Indications for use

α-BSM Bone Substitute Material is indicated for filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. α-BSM Bone Substitute Material is a bone graft substitute that resorbs and is replaced with bone during the healing process.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072636

Prescription Use ✓ OR Over-The Counter Use _____

(Per 21 CFR 801.109)